



December 13, 2002

## President Delivers Remarks on Smallpox

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### Protecting Americans: Smallpox Vaccination Program

Today, the President announced a plan to better protect the American people against the threat of smallpox attack by hostile groups or governments:

- **Smallpox Response Teams**

Under the plan, the Department of Health and Human Services (HHS) will work with state and local governments to form volunteer Smallpox Response Teams who can provide critical services to their fellow Americans in the event of a smallpox attack.

To ensure that Smallpox Response Teams can mobilize immediately in an emergency, health care workers and other critical personnel will be asked to volunteer to receive the smallpox vaccine.

The federal government is not recommending vaccination for the general public at this time. There may be some members of the general public who insist on being vaccinated now. Our public health agencies will work to accommodate them, but that is not our recommendation at this time.

- **Department of Defense and State Department Personnel**

The President also announced that the Department of Defense (DOD) will vaccinate certain military and civilian personnel who are or may be deployed in high threat areas. Some United States personnel assigned to certain overseas embassies will also be offered vaccination.

### STRENGTHENING HOMELAND SECURITY

Although there is **no reason to believe that smallpox presents an imminent threat**, the attacks of September and October, 2001 have heightened concern that

terrorists may have access to the virus and attempt to use it against the American public. Immediately after these attacks, HHS began working, in cooperation with state and local governments, to strengthen our preparedness for bioterror attacks by expanding the national stockpile of smallpox vaccine. **The United States currently has sufficient quantities of the vaccine to vaccinate every single person in the country in an emergency.**

The smallpox vaccine, which was routinely administered to Americans until 1972, is a highly effective protection against the disease when given before or shortly after exposure to the virus. Pre-attack vaccination of Smallpox Response Teams will allow them, in the event of a smallpox attack, to immediately administer the vaccine to others and care for victims.

HHS is working with states to identify health care workers and first responders to serve on Smallpox Response Teams. Pre-attack vaccination of these teams Smallpox Response Teams will allow them to better protect the American public against smallpox attack.

The federal government is not recommending that members of the general public be vaccinated at this point. Our government has no information that a biological attack is imminent, and there are significant side effects and risks associated with the vaccine. HHS is in the process of establishing an orderly process to make unlicensed vaccine available to those adult members of the general public without medical contraindications who insist on being vaccinated either in 2003, with an unlicensed vaccine, or in 2004, with a licensed vaccine. (A member of the general public may also be eligible to volunteer for an on-going clinical trial for next generation vaccines).

## **PREPARING MILITARY AND OVERSEAS PERSONNEL**

The President also announced that DOD will take steps immediately to reinstitute vaccination of certain military and civilian personnel. Those personnel who are deployed or who may deploy to certain high threat areas will be vaccinated. The State Department will also offer vaccination to certain overseas personnel.

Although the vaccine is effective if administered shortly after exposure, it may not be feasible during an emergency to vaccinate overseas troops and civilian personnel. Pre-attack vaccination is therefore warranted. Vaccination of military personnel was conducted during WWI and WWII and routinely from the 1940s until 1984. Between 1984 and 1990, vaccinations were provided to many recruits entering basic training.

## **Frequently Asked Questions**

### **Smallpox Response Teams**

#### **Why vaccinate health care workers and first responders?**

We're asking these groups to volunteer to serve on smallpox response teams to help our country respond in the event of an attack. By vaccinating groups of health care workers and emergency

responders, we will make sure that smallpox response teams are available who can vaccinate others and provide critical services in the days following an attack. This approach will make us better able to protect the American people in an emergency, which is our highest priority.

### **What will the smallpox response teams do?**

Members of the Smallpox Response Teams will include people who will administer the smallpox vaccine in the event of an emergency and will be the first to investigate and evaluate initial suspected case(s) of smallpox and initiate measures to control the outbreak.

HHS and CDC will continue to advise and assist states in development of these teams.

### **How will the government decide who should serve on a smallpox response team?**

State officials – in consultation with CDC and local health departments – are working to identify health care workers and first responders who could serve on response teams following a smallpox release. Participation on these teams and in the vaccination program is purely voluntary.

### **How many first responders and health care workers will be vaccinated?**

We have asked states to identify workers who might serve on smallpox response teams to vaccinate others and provide critical services in the days following an attack. We are working with states to determine the exact number of individuals who will fall in these categories. To protect the American people, the important thing is to ensure that we have health care workers and first responders ready to serve as smallpox response teams. However, we expect that some of the people identified by the states will not be eligible for vaccination because of a medical condition, and others may choose not to be vaccinated.

It has been reported that we will be vaccinating up to 10 million health care workers and first responders. However, we do not expect that the numbers of first responders and health care workers vaccinated in this part of the program to be that high.

### **Are we less prepared to protect the American people if we don't get participation from millions of public health and health care workers or first responders?**

Whatever the number of people who choose to participate and get vaccinated, we will be much more prepared to protect the American people than we are today.

Also, the very fact that states, hospitals and communities will have vaccination plans – for emergency responders and for mass-vaccinating the general public – makes us better prepared to protect Americans in an emergency.

These efforts will increase deterrence.

### **Will you administer tests to ensure that health care workers and first responders receiving the vaccine are not pregnant or HIV positive?**

Every person volunteering to receive the vaccine will be asked detailed questions regarding their medical history and physical health and will be educated to the risks and possible side effects of the vaccine. If there is any indication that a person has a contraindication for the vaccine, the individual will be referred to the local public health department or another health care provider for testing.

**How can a person protect against the risk of inadvertent transmission of the vaccine to another person?**

Anyone receiving the vaccine will be instructed on several readily available steps to prevent the accidental transmission of the vaccine to another person. For example, the vaccinated person should use breathable bandages, wear a long-sleeve shirt, and use good hand hygiene.

**How will the government monitor and report side effects?**

The CDC is enlisting an outside group that will constitute an external data monitoring and safety review board. This external review board will review, in real time, vaccine adverse event reports and data, interpret findings, and provide guidance and advice for strengthening the overall safety of the program if needed.

**How does this decision differ from the vaccination program in Israel? The vaccination program in the U.K.?**

Israel is vaccinating health care workers and military personnel who were previously vaccinated. In the U.K., a small group of roughly 1000 people are being vaccinated.

**Is it true that those who were vaccinated previously have a lower risk of adverse reaction?**

Those who were vaccinated previously may have a lower risk of adverse reactions. It is appropriate for individuals, in deciding whether to be vaccinated, to consider whether they were vaccinated previously.

**How will vaccine adverse events be handled? What protocols will be followed for actual or claimed serious adverse events?**

Prospective vaccinees will be educated about the contraindications to smallpox vaccination in order to minimize serious adverse reactions to the vaccine. A good system to monitor and treat adverse events will be an integral part of this policy, and will be done in close collaboration between the CDC, states, and public health agencies and hospitals. The states will maintain records of people vaccinated and will work with hospitals to set up systems to diagnose, manage, and treat people who experience adverse reactions from the vaccine. This will include rapid access to the primary treatment for most serious adverse events, Vaccinia Immune Globulin (VIG).

It is expected that most of the side effects caused by smallpox vaccinations will not require special treatment or therapy. There are two treatments that may help people who have certain serious reactions to the smallpox vaccine. These are: Vaccinia Immune Globulin (VIG) and Cidofovir. Patients receiving these drugs would need to stay in the hospital for observation and possible additional treatment, as the VIG and Cidofovir may cause a number of side effects as well. CDC will review summary reports of adverse events and will investigate all individual reports of serious events.

**General Public**

**What is the current threat assessment? Who are likely countries to obtain and use the virus?**

Terrorists or governments hostile to the United States may have, or could obtain, some of the variola virus that causes smallpox disease. If so, these adversaries could use it as a biological

weapon. This potential along with an appreciation for the potentially devastating consequences of a smallpox attack, suggests that we should take prudent steps to prepare our critical responders to protect the American public should an attack occur. People exposed to variola virus, or those at risk of being exposed, can be protected by vaccinia (smallpox) vaccine. The United States is taking precautions to deal with this possibility.

**If a person wants to sign up to receive the vaccine as soon as possible, what should they do?**

The federal government is not recommending that members of the general public be vaccinated at this point. Our government has no information that a biological attack is imminent, and there are significant side effects and risks associated with the vaccine. HHS is in the process of establishing an orderly process to make unlicensed vaccine available to those adult members of the general public without medical contraindications who insist on being vaccinated either in 2003, with an unlicensed vaccine, or in 2004, with a licensed vaccine. (A member of the general public may also be eligible to volunteer for an on-going clinical trial for next generation vaccines).

**How long will it take before HHS begins administering vaccines to the general public under the new program?**

Again, we do not recommend at this point that the general public be vaccinated. However, we expect to be able to make the unlicensed vaccine available to those who insist on being vaccinated sometime this spring. The immediate task for state and federal government will remain the implementation of our program to vaccinate our emergency responders. This is necessary to best protect Americans in the event of a release.

Of course, in the event of an actual attack, we will immediately make vaccine available to those at risk from disease.

**Who will administer the vaccines?**

State health departments, with guidance from CDC, will set up vaccination clinics and determine who will be staffing clinics and administering smallpox vaccine. The number of vaccination sites will be determined in the state plans, and depends in large part on the demand for the vaccines. CDC is assisting states with planning, technical assistance and education.

**If you aren't recommending that the general public be vaccinated, why are you setting up this special program to allow them to get the vaccine?**

We understand that some Americans will want to be vaccinated despite the risks. The President decided that the best course was to provide Americans with as much information as we can, help them weigh the risks, then let them decide for themselves.

**Will you administer tests to ensure that members of the general public receiving the vaccine are not pregnant or HIV positive?**

Every person volunteering to receive the vaccine will be asked detailed questions regarding their medical history and physical health. They will be educated to the risks and possible side effects of the vaccine. If there is any indication that a person has a contraindication for the vaccine, the individual will be referred to the local public health department or another health care provider for testing.

**How will the government monitor and report side effects?**

The CDC will enlist an outside group to constitute an external data monitoring and safety review board. This external review board will review vaccine adverse event reports and data, interpret findings, and provide guidance and advice for strengthening the overall safety of the program.

## **Military Personnel**

### **Why are we vaccinating servicemembers?**

We are concerned that terrorists or governments hostile to the United States may have, or could obtain, some of the variola virus that causes smallpox disease. If so, these adversaries could use it as a biological weapon. People exposed to variola virus, or those at risk of being exposed, can be protected by vaccinia (smallpox) vaccine.

### **Who in DoD is going to get the smallpox vaccine?**

As part of this plan, the decision at this time is to vaccinate certain emergency response and medical personnel and other designated personnel that constitute critical mission capabilities, to include those essential to the accomplishment of U.S. Central Command's missions. The Department may expand the program at a later date.

The decision will be implemented using a portion of the existing licensed supplies of smallpox vaccine.

### **Will servicemembers still be deployable if they have not received the smallpox vaccine?**

Yes, if they are in one of the groups that should not receive the smallpox vaccine they will still be deployable. In the event of an actual smallpox attack their vaccination status will be reevaluated.

### **When are the smallpox vaccinations going to start?**

Smallpox vaccinations of DOD personnel will begin as soon as the vaccine is in place and medical training and troop education have been accomplished.

### **Has the Department of Defense vaccinated people against smallpox before?**

Yes, the Department conducted major vaccination programs during WWI and WWII and servicemembers were routinely vaccinated from the 1940s until 1984. In 1984, routine military vaccinations were limited to recruits entering basic training. Between 1984 and 1990, recruit vaccinations were intermittent. In 1990, the Department of Defense discontinued vaccination of recruits.

### **How does the threat of a smallpox attack on US forces compare with that of an anthrax attack?**

They are both known threats. Many factors go into such determinations including intelligence information, known capabilities and other variables. While we cannot quantify the threat of either one being used as a bioweapon, we know the consequences of their use could be great. Vaccination is a wise, logical step to ensure preparedness for the U.S.

### **Will the people receiving anthrax vaccinations be the same ones receiving the smallpox vaccinations?**

Generally speaking, forces currently designated to receive anthrax vaccine also will receive smallpox vaccine. Additional forces will be vaccinated against smallpox given that smallpox, unlike anthrax, is contagious and can be prevented only with vaccine. The Secretary of Defense may decide in the future to expand the scope of both the anthrax and smallpox vaccination programs.

### **How does the smallpox vaccination interact with other drugs and vaccinations?**

The smallpox vaccine should not be given to people taking medications that suppress their immune system. Smallpox vaccines should be spaced by one month from chickenpox vaccination. Other combinations of vaccines (e.g. smallpox and influenza or smallpox and anthrax) can be given.

### **Why is the Department of Defense administering the smallpox vaccine?**

We cannot quantify the threat that smallpox would be used as a bioweapon, but we do know that the consequences of its use could be great. Military missions must go on even if a smallpox outbreak occurs. It may not be feasible to vaccinate military forces soon after exposure if they are deployed to remote locations and/or engaged in military operations. Some military personnel will not be able to postpone vital missions if smallpox is used as a weapon. Vaccination is a wise course for preparedness and may serve as a deterrent.

### **What should a person do if they don't get a blister?**

If someone does not get the expected vaccination site reaction, they need to be revaccinated. If someone has a question or concern about the smallpox vaccination site they should contact their primary-care manager, medical department representative or their healthcare provider.

### **What should a person do if they have any adverse reactions?**

If a person suspects an adverse reaction from the smallpox vaccine he or she should seek care from their primary-care manager, medical department representative, or go to their healthcare provider as soon as possible.

They should request that their healthcare provider file a Vaccine Adverse Event Reporting System (VAERS) form. If they don't believe their reaction is serious enough to visit a medical treatment facility, but they still wish to report it, they can contact VAERS themselves at 1.800.822.7967 or file a report at the following Web site: [www.vaers.org](http://www.vaers.org).

### **What if somebody has already been vaccinated?**

Immunity from smallpox vaccination decreases with the passage of time. Past experience indicates that the first dose of the vaccine offers protection from smallpox for three to five years, with decreasing immunity thereafter. If a person is vaccinated again later, immunity lasts longer. A report from Europe suggests that people vaccinated 10 or 20 or more years ago have enough immunity to lessen their chance of death if infected. However, these people need another dose of smallpox vaccine to restore their immunity.

## **State Department and Overseas Issues**

### **Has the Department decided to vaccinate its personnel against smallpox or anthrax?**

The Department plans to offer, on a voluntary basis, vaccination against anthrax and smallpox to personnel at certain posts.

While it is impossible to quantify the threat that such bio-weapons could be used, we know that the consequences of such use could be very grave. In that context, the Department believes offering the vaccine is a wise step.

**What if someone cannot take the vaccine? Is the Department planning to evacuate those persons?**

Pre-exposure administration of the vaccines is considered the most effective means to protect against these two health risks. However, we understand that there will be a number of people who cannot, or opt not to, receive the vaccines. We will be prepared to offer the vaccines or other appropriate treatment in the event of actual exposure.

**Does Iraq have smallpox? Do you believe that Iraq may use a smallpox weapon if attacked by the United States?**

It is possible, but not confirmed, that Iraq possesses the virus that causes smallpox. By protecting ourselves to respond to any smallpox attack, including through pre-exposure and post-exposure vaccination plans, we also help deter such attacks.

**What is the Department planning to do for private American citizens in that region?**

We provide extensive information to the American public about travel, security, health, and other conditions abroad to assist private Americans in making individual decisions about their own security and risks. We are following the same approach in this instance.

**Has the Department told American citizens to leave the Middle East because of these biological threats? Have any warden messages been prepared for a possible attack?**

The Department of State has issued a Worldwide Caution Public Announcement and a Middle East and North Africa Update that alerts American citizens to the continuing threat of terrorist actions that may target private Americans. The Department of State works with posts to disseminate threat information through its warden network when specific information is available. At present, there is no specific information to indicate that there is a likelihood of use of anthrax or smallpox as a weapon in the immediate future. Also, a Chemical-Biological Agent Fact Sheet, which includes information on anthrax and smallpox, is available on the Consular Affairs website at: <http://travel.state.gov>.

**Are we planning to assist any other country in obtaining supplies of vaccines?**

The United States recognizes that a smallpox attack in any nation is a potential threat to all nations. The United States, therefore, will work with like-minded nations and the World Health Organization (WHO) to facilitate and coordinate nations' access to existing global smallpox vaccine supplies and to increase the global supply through new production.

**Will smallpox vaccine be provided to other countries for their civilian populations?**

The United States will work with like-minded nations and the WHO to facilitate and coordinate nations' access to existing global smallpox vaccine supplies and to increase the global supply through new production.



**Will the United States assist nations in the event of an actual smallpox or anthrax attack?**

Recognizing the global threat posed by a bio-weapon attack, the U.S. Government stands prepared to lend all feasible assistance in the event of an actual anthrax or smallpox attack against a country.